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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/905,709	08/05/1997	DAVID STERN	52876/JPW/JM	5754

7590 03/18/2005

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NEW YORK, NY 10036

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/905,709	STERN ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8,9,15-18,36,37 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,9,15-18,36,37 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/2004 has been entered.

Applicants' supplemental communication regarding examiners' interview filed on August 17, 2004 has been made of record.

Claims 5-7, 10-14, 19-35 and 38-39 are canceled and claims 40-45 are withdrawn.

Claims 1-4, 8, 9, 15-18, 36, 37 and 46 are pending and under examination.

In view of Applicants' response, and upon further reconsideration of lack of prima facie under 35 USC § 112-enablement for a method of inhibiting atherosclerosis in a subject comprising administering the sRAGE as set forth in the previous office action for determination of priority (paper mailed on 11/12/2003), the rejection of claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 USC 102(e) is being withdrawn. However, due to the lack of adequate written support in the '070' for the claimed invention of the instant application as set forth below, the priority of the instant application is the filing date of the instant application which is 05/08/1997.

The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action.

Priority

The '070' application does not describe the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The '070' specification discloses a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia comprising administering to the subject a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting an interaction between amyloid- β peptide and RAGE in an amount effective to inhibit atherosclerosis. The specification of the '070' application describes that the blocking peptide can also be an agent such as an antibody or a portion of an antibody that specifically to the sRAGE (page 11, line 26-32). However, the '070' specification provides no support for a derivative of sRAGE in the '070' application as being instantly claimed. Therefore, the priority of the instant application is the filing date of the instant application which is 05/08/1997.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 9, 15-18, 36, 37 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia comprising administering to the subject a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting an interaction AGE and RAGE in an amount effective to inhibit atherosclerosis in an obese diabetic subject.

To provide undisclosed possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics for the invention. The factors to be considered include disclosure of complete functional characteristics, function correlation, method of making an invention, method of treatment, or any combination thereof. The instant application discloses that a derivative can be a polypeptide, a peptidomimetic compound having the biological activity of inhibiting atheroscerosis (pages 9-13). Applicants do not provide a definition of " a derivative" or disclose any derivative, if they had at the time of filing of the instant application. As such derivatives of sRAGE encompasses a huge number of substitutions, insertions, deletions, mutations and an attachment of modifying groups of sRAGE. Thus, the claims are drawn to a genus of sRAGE.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

As discussed above, the skilled artisan cannot envision the detailed underlying mode of making innumerable derivatives of sRAGE, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of achieving it.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicants' response in directing to the amino acid sequence of sRAGE in Table-1 of the instant application, the rejection of claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 USC § 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-4, 8, 9, 15-18, 36, 37 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Morser et.al. (US Patent No. 5,864,018). as set forth in the previous office action (4/23/2002), is maintained for the reasons of record. Applicants' arguments have been fully considered but they are not persuasive.

The claims are drawn to a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia comprising administering to the subject a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting an interaction AGE and RAGE in an amount effective to inhibit atherosclerosis in an obese diabetic subject.

Applicants argue that the rejection can be overcome by perfecting priority under 35 USC § 120 amending specification so as to the claim priority to the '070' application. Applicants' arguments have been fully considered but they are not persuasive for the reason set forth supra. Therefore, the rejection under 35 U.S.C. 102(e) is valid and applied here.

Morser et.al. teach that the soluble RAGE polypeptides can be used for the treatment of an obese diabetic subject suffering from complications associated with diabetes such as atherosclerosis and occlusive vascular disorders (column 19, line 6-15). They also teach the pharmaceutical composition, an effective amount of

composition (from 0.0001 to 10 mg/kg) and methods of administration (see, column 19, line 45-65) for treating atherosclerosis. Further, they teach that the composition can comprise a pharmaceutically acceptable carrier and that it can be administered by a method of oral, intravenous, or through a controlled release device (column 20, lines 1-10).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
10 February 2005

SUPERVISORY PATENT EXAMINER
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